APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 74-1129

SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATI
1075 Central Park Avenue
Scarsdale, New York 10583

DRY COLOR MANUFACTURERS ASSOCIATION, INC.
561 Franklin Avenue
Nutley, New Jersey 07110

AMERICAN DYE MANUFACTURERS INSTITUTE, INC.
74 Trinity Place
New York, New York 10006

AMERICAN CYANAMID COMPANY
Bound Brook, New Jersey 08805

INMONT CORPORATION
1255 Broad Street
Clifton, New Jersey 07016

UNION CARBIDE CORPORATION
270 Park Avenue
New York, New York 10017

CELANESE CORPORATION
522 Fifth Avenue
New York, New York 10036

ALLIED CHEMICAL CORPORATION
Post Office Box 1219 R
Morristown, New Jersey 07960

DOW CHEMICAL U.S.A.
2020 Abbott Road Central
Midland, Michigan 48640

AEROJET-GENERAL CORPORATION
Post Office Box 702
Elmonte, California 91734

PFISTER CHEMICAL, INC.
Ridgefield, New Jersey 07656

CROMPTON & KNOWLES CORPORATION
Route 208
Fair Lawn, New Jersey 07410,

Petitioners,

v.

PETER J. BRENNAN, Secretary, Department of Labor, and JOHN H. STENDER, Assistant Secretary of Labor for Occupational Safety and Health,

Respondents.

ON PETITION FOR REVIEW OF ACTION OF THE ASSISTANT SECRETARY OF LABOR FOR OCCUPATIONAL SAFETY AND HEALTH

Argued June 13, 1974

Before STALEY, GIBBONS and WEIS, *Circuit Judges.*

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Charles F. Lettow
Donald L. Morgan
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Department of Justice
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Attorneys for Respondent

OPINION OF THE COURT

(Filed August 26, 1974)

By STALEY, *Circuit Judge.*

This case is before the court upon petition to review an order of the Assistant Secretary of Labor for Occupational Safety and Health, published on January 29, 1974, 39 Fed. Reg. 3756, issuing permanent occupational health standards which regulate, *inter alia,* employee exposure to solid or liquid mixtures containing one percent or more of ethyleneimine ("EI"). See 29 C.F.R. § 1910.93*lc.*[1] This court has jurisdiction to review and set aside these standards pursuant to § 6(f) of the Occupational Safety and Health Act of 1970, 29 U.S.C. § 655(f) ("Act").

The standards in question are part of a group of permanent standards simultaneously issued pursuant of § 6(b) of the Act. 29 U.S.C. § 655(b). They were derived from similar emergency temporary standards issued on May 3, 1973, 38 Fed. Reg. 10929. This court has previously vacated and remanded to the Occupational Safety and Health Administration ("OSHA") the temporary standards in so far as they applied to EI and one other chemical. Dry Color Manufacturers' Association, Inc. v. Department of Labor, 486 F.2d 98 (C.A. 3, 1973). We must now consider the permanent standards relating to EI.

On review the petitioners request that the court set aside OSHA's standards applicable to EI. They challenge the validity of the standards on three principal grounds. They maintain that there is not substantial evidence to show that EI is carcinogenic; that the record does not support the particular EI standards; and that the Secretary

[1] We are presently considering only the EI standards. The petition as originally filed requested review of the standards for other substances as well as those relating to EI. This court, however, ordered a separate consideration of the EI standards and stayed them pending this determination of the merits of the case.

failed to make sufficient findings of fact or to provide sufficient statements of reasons for the standards.

We deal first with the petitioners' last contention. Subsection 6(e) of the Act provides:

> "Whenever the Secretary promulgates any standard, . . . he shall include a statement of the reasons for such action, which shall be published in the Federal Register." 29 U.S.C. § 655(e).

As this court has previously stated, to satisfy subsection 6(e) the statement of reasons should indicate which data in the record is being relied upon, why that data shows the substances regulated are harmful, and why the particular standards were chosen. Dry Color Manufacturers' Assn., Inc. v. Department of Labor, 486 F.2d at 106. In that case a temporary emergency standard for the control of EI was invalidated by this court because the Secretary, in promulgating it, had not provided an adequate statement of reasons.

In the instant case, the statement of reasons offered by OSHA, published January 29, 1974, 39 Fed. Reg. 3756, consisted in part of the finding that EI was potentially carcinogenic to humans. In addition, according to OSHA, the case for EI's carcinogenicity rested on the extrapolation to humans of the findings of two animal studies. The Secretary justifies such an extrapolation on the basis of the April 22, 1970 Report of the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens to the Surgeon General. We have carefully examined the statements as well as those relating to the adopted standards themselves and conclude that they satisfy the requisites of subsection 6(e). We turn now to a consideration of the evidence in the record.

Subsection 6(f) directs courts reviewing a standard that "[t]he determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole." 29 U.S.C. § 655(f). See Industrial

Union Department, AFL-CIO v. Hodgson, — F.2d — (C.A. D.C. 1974); Associated Industries of New York State, Inc. v. United States Department of Labor, 487 F.2d 342 (C.A. 2, 1973). We find it extraordinarily difficult to apply this standard in this case. Section 6(a) of the Act directs the Secretary of Labor to promulgate by rule an occupational safety or health "standard which assures the greatest protection of the safety or health of the affected employees." 29 U.S.C. § 655(a). Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5) directs that

> "The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents . . . shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life."

Because the *Dry Color* case turned on noncompliance with § 6(e), it did not present us with an occasion to discuss the standard for review of informal rule making by the Secretary under the Act. However, the instant case requires that we do so.

It is made clear in § 6(b) that § 6(a) standards may be adopted by notice and comment rule making analogous to that provided for by § 4 of the Administrative Procedure Act, 5 U.S.C. § 553. Yet the quoted language of § 6(f) appears to limit judicial review to the scope of review which ordinarily applies to administrative determinations resulting from formal adjudications. *See* 5 U.S.C. § 706(2)(E). Compounding the confusion, § 10 of the Act, 29 U.S.C. § 659, provides for adjudications, § 11, 29 U.S.C. § 660, provides for judicial review of adjudications, and the wording of the standard for review of adjudicatory findings set forth in § 11(a) is virtually the same as that for review of informal rule making set forth in § 6(f). See Brennan v. Occupational Safety & Health Review Commission (Hanovia Lamp), No. 73-1131 (C.A. 3, filed—1974). It is clear that

application of the substantial evidence test to informal rule making was a deliberate legislative compromise between the House and Senate versions of the bill which became law. *See* the legislative history in Judge Friendly's opinion in Associated Industries of New York State, Inc. v. United States Department of Labor, 487 F.2d 342, 348-49 (C.A. 2, 1973).

How a reviewing court applies the substantial evidence test in reviewing quasi-legislative informal rule making is an intriguing problem which is just beginning to generate what will prove to be, we suspect, an extensive literature. In Associated Industries of New York State, Inc. v. United States Department of Labor, supra, Judge Friendly suggests that the difference between the substantial evidence test and the more traditional abuse of discretion test in the context of informal rule making may be largely semantic. 487 F.2d at 349-50. In Florida Peach Growers Association, Inc. v. United States Department of Labor, 489 F.2d 120, 129 (C.A. 5, 1974), Judge Roney writes:

> "[I]t seems clear that even with the required substantial evidence test, our review basically must determine whether the Secretary carried out his essentially legislative task in a manner reasonable under the state of the record before him."

In Industrial Union Department, AFL-CIO v. Hodgson, — F.2d — (C.A. D.C. 1974), Judge McGowan distinguished those rule making issues which were susceptible of resolution on a factual record, as to which the court would review for substantial evidence and those issues which by their nature were not capable of such resolution but represented policy judgments. As to the latter, Judge McGowan suggested that the Secretary's policy judgment would be affirmed if he indicated that factual certainty was not possible and identified rationally the controlling considerations. *But cf.* Environmental Defense Fund, Inc. v. Environmental Protection Agency, 489 F.2d 1247 (C.A. D.C. 1973)

and International Harvester Co. v. Ruckelshaus, 478 F.2d 615 (C.A. D.C. 1973).

This case is a good illustration of the difficulty of attempting to measure a legislative policy decision against a factual yardstick. OSHA's position with respect to EI is bottomed on an extrapolation from data gathered in two animal studies. The first is a study carried out in 1954 by Walpole which concluded that EI may be regarded as carcinogenic in rats and mice.[2] The Innes study, the second upon which OSHA relied, concluded that mice under experimental exposure to EI developed tumors with "malignant potentiality."[3] The extrapolation from the data gathered in these rodent experiments to humans is justified by the Report of the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens to the Surgeon General. This report states:

> "Any substance which is shown conclusively to cause tumors in animals should be considered carcinogenic and therefore a potential cancer hazard for man."

If the issue to be reviewed were merely whether EI was carcinogenic in rats and mice, we believe that we could point to the Walpole and Innes studies and safely conclude that the Secretary's determination of animal carcinogenicity was supported by substantial evidence. But the extrapolation of that determination from animals to humans is not really a factual matter. The Secretary's § 6(e) statement puts it thus:

> "Extrapolation of results obtained by animal experimentation is alleged to be vitiated by several considerations: (a) That certain cancers are specific only to

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[2] Walpole, Roberts, Rose, Hendry, and Homer, Cytotoxic Agents: IV. The Carcinogenic Actions of Some Monofunctional Ethyleneimine Derivatives, 9 Brit. J. Pharmacol. 306 (1954).

[3] Innes, et al., Bioassay of Pesticides and Industrial Chemicals for Tumorigenicity in Mice: A Preliminary Note, 42 J. Nat'l. Cancer Inst. 1101 (1969).

some species; (b) that the conditions of animal experiments are out of proportion to, and not consistent with, conditions prevailing in industrial exposure; and (c) that no cancers have yet been detected in humans exposed to the substances.

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"The objections raise the much broader issue of human exposure to a chemical which is only known to have caused cancers in experimental animals.

• • •

"We think it improper to afford less protection to workers when exposed to substances found to be carcinogenic only in experimental animals. Once the carcinogenicity of a substance has been demonstrated in animal experiments, the practical regulatory alternatives are to consider them either non-carcinogenic or carcinogenic to humans, until evidence to the contrary is produced. The first alternative would logically require, not relaxed controls on exposure, but exclusion from regulation. The other alternative logically leads to the treatment of a substance as if it was known to be carcinogenic in man.

"We agree with the director of NIOSH and the report of the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens to the Surgeon General, U.S. Public Health Service, April 22, 1970 that the second alternative is the responsible and correct one." (Appendix at 845-46.)

It seems to us that what the Secretary has done in extrapolating from animal studies to humans is to make a legal rather than a factual determination. He has said in effect that if carcinogenicity in two animal species is established, as a matter of law §§ 6(a) and 6(b)(5) require that they be treated as carcinogenic in man. This is in the nature of a recommendation for prudent legislative action.

This raises the problem of our role under § 6(f) in reviewing the Secretary's nonfactual policy decisions. The deliberate congressional choice of the substantial evidence standard for review might be interpreted to exclude us

from review of any but factual determinations and to require that we afford absolute deference to the Secretary's interpretation of the statute. However, no court that has considered the scope of judicial review has so read § 6(f). By one formulation or another each seems to have found room under § 6(f) for judicial review for consistency between the Secretary's rule and the statutory language and purpose. See Industrial Union Department, AFL-CIO v. Hodgson, supra; cf. Florida Peach Growers Association, Inc. v. United States Department of Labor, supra; Dry Color Manufacturers' Assn., Inc. v. Department of Labor, supra; Associated Industries of New York State, Inc. v. United States Department of Labor, supra. Undoubtedly, this approach is sound, for the last sentence of § 6(f) cannot be read in a vacuum. Meaning must be given to all of § 6. The last sentence of § 6(f) must be read together with the requirement in § 6(e) that the Secretary "include a statement of the reasons for such action which shall be published in the Federal Register." He is not directed to file findings of fact. His reasons for action may include policy determinations as well as factual findings. The requirement that he state reasons strongly suggests that those reasons, whether policy judgments or factual findings, may be subjected to judicial review. Moreover, there are different legal criteria for the adoption of emergency temporary standards than for the adoption of permanent standards, but § 6(f) provides for judicial review of both. Section 6(c)(1) authorizes adoption of emergency temporary standards when the Secretary "determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger." 29 U.S.C. § 655(c)(1). Permanent standards must assure " the greatest protection of the safety or health of the affected employees," 29 U.S.C. § 655(a), and, with respect to toxic substances, must "most adequately assure[s], to the extent feasible, on the basis of the best avail-

able evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." 29 U.S.C. § 655(b)(5). The very difference in the legal criteria suggests that the court in reviewing pursuant to § 6(f) must at a minimum determine if the Secretary applied the correct ones, and certainly, as we held in Dry Color Manufacturers' Assn., Inc. v. Department of Labor, supra, judicial review under § 6(f) encompasses our evaluation of the procedural requirements of § 6 even though our interpretation differs from that of the Secretary.

It seems, then, that judicial review of a § 6 standard properly includes at least the following:

(1) determining whether the Secretary's notice of proposed rule making adequately informed interested persons of the action taken;

(2) determining whether the Secretary's promulgation adequately sets forth reasons for his action;

(3) determining whether the statement of reasons reflects consideration of factors relevant under the statute;

(4) determining whether presently available alternatives were at least considered; and

(5) if the Secretary's determination is based in whole or in part on factual matters subject to evidentiary development, whether substantial evidence in the record as a whole supports the determination.

In the context of this case, all five steps are involved.

We note that there was a lack of notice regarding OSHA's plans to make special provisions regarding EI's use in research laboratories. The Secretary's notice did not advise that the agency planned to make special provisions regarding EI use in laboratories. Because of this,

we hold that to the extent that the standards in question relate to research laboratories, they will be vacated and remanded to OSHA. Further, as we concluded above, the statements of reasons reflect considerations relevant under §§ 6(a) and 6(b)(5) and are therefore sufficient under subsection 6(e). Lastly, we hold that there does exist substantial evidence in the record as a whole to support the Secretary's finding that EI is carcinogenic in rats and mice and in the absence of evidence of carcinogenicity in humans, the Secretary properly weighed the only available alternatives. We, therefore, reject the petitioners' challenge to the EI standards except in so far as they relate to laboratories as outlined above.

The cause will be remanded to OSHA with directions to proceed in conformity with this opinion.

APPENDIX B

Statute Involved

Occupational Safety and Health Act. Section 6 of the Occupational Safety and Health Act (29 U.S.C. § 655 (1970)) provides as follows:

> (a) *Without regard to chapter 5 of title 5, United States Code, or to the other subsections of this section,* the Secretary shall, as soon as practicable during the period beginning with the effective date of this Act and ending two years after such date, by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard, unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees. In the event of conflict among any such standards, the Secretary shall promulgate the standard which assures the greatest protection of the safety or health of the affected employees.
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> (b) The Secretary may by rule promulgate, modify, or revoke any occupational safety or health standard in the following manner:
>
> (1) Whenever the Secretary, upon the basis of information submitted to him in writing by an interested person, a representative of any organization of employers or employees, a nationally recognized standards-producing organization, the Secretary of Health, Education, and Welfare, the National Institute for Occupational Safety and Health, or a State or political subdivision, or on the basis of information developed by the Secretary or otherwise available to him, determines that a rule should be promulgated in order to serve the objectives of this Act, the Secretary may request the recommendations of an advisory committee appointed under section 7 of this Act. The

Secretary shall provide such an advisory committee with any proposals of his own or of the Secretary of Health, Education, and Welfare, together with all pertinent factual information developed by the Secretary or the Secretary of Health, Education, and Welfare, or otherwise available, including the results of research, demonstrations, and experiments. An advisory committee shall submit to the Secretary its recommendations regarding the rule to be promulgated within ninety days from the date of its appointment or within such longer or shorter period as may be prescribed by the Secretary, but in no event for a period which is longer than two hundred and seventy days.

(2) The Secretary shall publish a proposed rule promulgating, modifying, or revoking an occupational safety or health standard in the Federal Register and shall afford interested persons a period of thirty days after publication to submit written data or comments. Where an advisory committee is appointed and the Secretary determines that a rule should be issued, he shall publish the proposed rule within sixty days after the submission of the advisory committee's recommendations or the expiration of the period prescribed by the Secretary for such submission.

(3) On or before the last day of the period provided for the submission of written data or comments under paragraph (2), any interested person may file with the Secretary written objections to the proposed rule, stating the grounds therefor and requesting a public hearing on such objections. Within thirty days after the last day for filing such objections, the Secretary shall publish in the Federal Register a notice specifying the occupational safety or health standard to which objections have been filed and a hearing requested, and specifying a time and place for such hearing.

(4) Within sixty days after the expiration of the period provided for the submission of written data or comments under paragraph (2), or within sixty days after the completion of any hearing held under paragraph (3), the Secretary shall issue a rule promulgating, modifying, or revoking an occupational safety or health standard or make a determination that a rule should not be issued. Such a rule may contain a provision delaying its effective date for such period (not in excess of ninety days) as the Secretary determines may be necessary to insure that affected employers and employees will be informed of the existence of the standard and of its terms and that employers affected are given an opportunity to familiarize themselves and their employees with the existence of the requirements of the standard.

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

(6)(A) Any employer may apply to the Secretary for a temporary order granting a variance from a standard or any provision thereof promulgated under this section. Such temporary order shall be granted only if the employer files an application which meets the requirements of clause (B) and establishes that (i) he is unable to comply with a standard by its effective date because of unavailability of professional or technical personnel or of materials and equipment needed to come into compliance with the standard or because necessary construction or alteration of facilities cannot be completed by the effective date, (ii) he is taking all available steps to safeguard his employees against the hazards covered by the standard, and (iii) he has an effective program for coming into compliance with the standard as quickly as practicable. Any temporary order issued under this paragraph shall prescribe the practices, means, methods, operations, and processes which the employer must adopt and use while the order is in effect and state in detail his program for coming into compliance with the standard. Such a temporary order may be granted only after notice to employees and an opportunity for a hearing: *Provided*, That the Secretary may issue one interim order to be effective until a decision is made on the basis of the hearing. No temporary order may be in effect for longer than the period needed by the employer to achieve compliance with the standard or one year, whichever is shorter, except that such an order may be renewed not more than twice (I) so long as the requirements of this paragraph are met and (II) if an application for renewal is filed at least 90 days prior to the expiration date of the order. No interim renewal of an order may remain in effect for longer than 180 days.

(B) An application for a temporary order under this paragraph (6) shall contain:

(i) a specification of the standard or portion thereof from which the employer seeks a variance,

(ii) a representation by the employer, supported by representations from qualified persons having firsthand knowledge of the facts represented, that he is unable to comply with the standard or portion thereof and a detailed statement of the reasons therefor,

(iii) a statement of the steps he has taken and will take (with specific dates) to protect employees against the hazard covered by the standard,

(iv) a statement of when he expects to be able to comply with the standard and what steps he has taken and what steps he will take (with dates specified) to come into compliance with the standard, and

(v) a certification that he has informed his employees of the application by giving a copy thereof to their authorized representative, posting a statement giving a summary of the application and specifying where a copy may be examined at the place or places where notices to employees are normally posted, and by other appropriate means.

A description of how employees have been informed shall be contained in the certification. The information to employees shall also inform them of their right to petition the Secretary for a hearing.

(C) The Secretary is authorized to grant a variance from any standard or portion thereof whenever he determines, or the Secretary of Health, Education, and Welfare certifies, that such variance is necessary to

permit an employer to participate in an experiment approved by him or the Secretary of Health, Education, and Welfare designed to demonstrate or validate new and improved techniques to safeguard the health or safety of workers.

(7) Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate, such standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees. In addition, where appropriate, any such standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure. In the event such medical examinations are in the nature of research, as determined by the Secretary of Health, Education, and Welfare, such examinations may be furnished at the expense of the Secretary of Health, Education, and Welfare. The results of such examinations or tests shall be furnished only to the Secretary or the Secretary of Health, Education, and Welfare, and, at the request of the employee, to his physician. The Secretary, in consultation with the Secretary of Health, Education, and Welfare, may by rule promulgated pursuant to section 553 of title 5, United States Code, make appropriate modifications

in the foregoing requirements relating to the use of labels or other forms of warning, monitoring or measuring, and medical examinations, as may be warranted by experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard.

(8) Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard.

(c)(1) The Secretary shall provide, without regard to the requirements of chapter 5, title 5, United States Code, for an emergency temporary standard to take immediate effect upon publication in the Federal Register if he determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger.

(2) Such standard shall be effective until superseded by a standard promulgated in accordance with the procedures prescribed in paragraph (3) of this subsection.

(3) Upon publication of such standard in the Federal Register the Secretary shall commence a proceeding in accordance with section 6(b) of this Act, and the standard as published shall also serve as a proposed rule for the proceeding. The Secretary shall promulgate a standard under this paragraph no later than six months after publication of the emergency standard as provided in paragraph (2) of this subsection.

(d) Any affected employer may apply to the Secretary for a rule or order for a variance from a standard promulgated under this section. Affected employees shall be given notice of each such application and an opportunity to participate in a hearing. The Secretary shall issue such rule or order if he determines on the record, after opportunity for an inspection where appropriate and a hearing, that the proponent of the variance has demonstrated by a preponderance of the evidence that the conditions, practices, means, methods, operations, or processes used or proposed to be used by an employer will provide employment and places of employment to his employees which are as safe and healthful as those which would prevail if he complied with the standard. The rule or order so issued shall prescribe the conditions the employer must maintain, and the practices, means, methods, operations, and processes which he must adopt and utilize to the extent they differ from the standard in question. Such a rule or order may be modified or revoked upon application by an employer, employees, or by the Secretary on his own motion, in the manner prescribed for its issuance under this subsection at any time after six months from its issuance.

(e) Whenever the Secretary promulgates any standard, makes any rule, order, or decision, grants any exemption or extension of time, or compromises, mitigates, or settles any penalty assessed under this Act, he shall include a statement of the reasons for such action, which shall be published in the Federal Register.

(f) Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States court of appeals

for the circuit wherein such person resides or has his principal place of business, for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The filing of such petition shall not, unless otherwise ordered by the court, operate as a stay of the standard. The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

(g) In determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments. The Secretary shall also give due regard to the recommendations of the Secretary of Health, Education, and Welfare regarding the need for mandatory standards in determining the priority for establishing such standards.

APPENDIX C

Regulation Involved

Occupational Safety and Health Standard. The Preamble and Order promulgating the Occupational Safety and Health Standard for Ethyleneimine, 29 C.F.R. § 1910.-93*l* (39 Fed. Reg. 3756, Jan. 29, 1974), provide as follows:

TITLE 29—LABOR

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Carcinogens

Pursuant to section 6(b) and (c) of the Williams-Steiger Occupational Safety and Health Act of 1970 (29 U.S.C. 655) and Secretary of Labor's Order No. 12-71 (36 FR 8754), Part 1910 of Title 29, Code of Federal Regulations, is hereby amended in the manner set forth below, in order to provide standards dealing with the exposure of employees to certain substances that are known to cause cancer.

Background. On May 22, 1972, the Deputy Assistant Secretary of Labor for Occupational Safety and Health requested information from the Director of the National Institute for Occupational Safety and Health (NIOSH) on nine substances alleged to be carcinogens. As part of his effort to gain the best available scientific data, the Director published on July 6, 1972, at 37 FR 13285, a request for information concerning 15 substances. The data, arguments, and conclusions received by NIOSH were made available to the Occupational Safety and Health Administration.

On January 4, 1973, a petition for an emergency temporary standard from the Oil, Chemical, and At-

omic Workers Union (OCAW) and Health Research Group (HRG) was received by the Department of Labor. The petition contained relevant information on the danger of exposure to 10 carcinogens, and suggested regulations to prevent worker exposure to the substances.

On February 9, 1973, a notice was published in the FEDERAL REGISTER (38 FR 4037) of the receipt of the petition for issuance of an emergency temporary standard, and information was requested from interested persons on the issues involved. In response to the notice, more than 50 written comments were received.

An emergency temporary standard on carcinogens was promulgated on May 3, 1973, at 38 FR 10929. The standard concerned work practices and controls designed to protect employees from exposure to 14 carcinogenic substances.

A standard advisory committee on carcinogens was appointed and began its meetings on June 25, 1973. The members of the committee represented employers, employees, Federal and state agencies and professionals. The committee terminated its meetings on August 24, 1973, and submitted to the Assistant Secretary of Labor for Occupational Safety and Health its recommendations for a standard on certain carcinogens on August 27, 1973. The recommendations were published in the FEDERAL REGISTER on September 7, 1973 (38 FR 24375).

This rulemaking proceeding was commenced under section 6(b) and (c) of the Act, with the emergency temporary standard serving as a proposal as required by section 6(c)(3) of the Act. Notice of the proceeding was published in the FEDERAL REGISTER on July 16, 1973 (38 FR 18900). On July 27, 1973, a revision of the emergency temporary standard was published at 38 FR 20074, and an amended notice of rulemaking pro-

ceeding was published at 38 FR 22141, on August 16, 1973.

The notices invited interested persons to submit, prior to September 5, written comments, data and arguments concerning the proposals, and also provided for the presentation of oral testimony at a public hearing scheduled for September 11-14, 1973. Numerous written comments were received and about 36 parties testified at the hearing. The record of the hearing was initially held open until September 28, for additional comments. After the close and certification of the record by the administrative law judge, additional comments mailed on or before September 28 were received. On October 2 the judge reopened the record for the limited purpose of including these additional comments. On October 15, the judge closed the proceeding and forwarded the certified record to the Assistant Secretary of Labor for Occupational Safety and Health for final decision.

A final environmental impact statement on the proposed standard on carcinogens was filed with the Council on Environmental Quality on October 2, 1973, and copies were distributed to appropriate agencies. In a letter dated November 2, 1973, the Council pointed out alleged deficiencies in the statement filed. Pursuant to that letter, a supplement to the statement was sent to the Council on November 29, 1973, with a request for a waiver of the full, 30-day review period. By letter dated December 10, 1973, the Council advised that the request had been denied. Notice of the filing of the supplement was published by the Council on December 14, 1973 (38 FR 34488).

The following are the major issues raised in the record of this proceeding:

(1) *Selection of carcinogens.* Some participants in this proceeding have demanded to know the criteria

for the selection of the 14 substances for regulation. As the written submission of Uniroyal Chemical notes, thirteen compounds derive from Appendix A to the 1972 TLV pamphlet published by the American Conference of Government Industrial Hygienists (ACGIH). Alpha-Naphthylamine, which is not in the appendix, has been added because it has frequently been found, in industrial experience and in epidemiologic studies, together with beta-naphthylamine, and because experimental animal studies demonstrate its independent carcinogenicity, Dimethyl sulfate, which is in the appendix, is not included in the standards because it was concluded after consideration of the relevant literature that the documentation of its carcinogenicity was inadequate. The substances listed by ACGIH (except one) were selected in order to take advantage of the work and judgment of that group. Also, ten of the fourteen substances were proposed to the Occupational Safety and Health Administration (OSHA) for regulation by OCAW and HRG in their petition.

(2) *Documentation of carcinogenicity.* The National Institute for Occupational Safety and Health (NIOSH), as official scientific advisor to OSHA, submitted to OSHA fourteen hazard review documents; one for each of the substances included in the standards. Each hazard review document contains a summary and evaluation of information and data obtained by NIOSH, including experimental animal and epidemiologic data. All but one of the substances are considered by ACGIH to be carcinogenic in man and/or animals.

In promulgating these standards, OSHA has relied extensively but not exclusively, on the hazard review documents prepared by NIOSH. Some of the substances are recognized as human carcinogens by some employers participating in this proceeding. For in-

stance, although Young Aniline Works apparently takes issue with the studies which demonstrated Benzidine to be a human carcinogen, the Benzidine Task Force of the Synthetic Organic Chemical Manufacturers Association does not oppose OSHA considering benzidine as carcinogenic to humans.

The essence of the NIOSH hazard review documents follows.

* * * * * * * * * *

Ethyleneimine. The carcinogenic potential of ethyleneimine (EI) has been confirmed by a study conducted by Walpole in 1954 involving rats and one sponsored by the National Cancer Institute involving mice. In the first study, animals developed injection site sarcomas which the investigators attributed to the direct action of Ethyleneimine, and in the second study 80 percent of the animals developed tumors, including more than one-half with hepatomas (which the investigators stated had "malignant potentiality"), and almost three-quarters with pulmonary tumors. Although high doses of EI were administered, the investigators stated there was no way to predict whether man would be more or less susceptible to tumor induction by EI.

The case for the carcinogenicity of EI, then, rests on the extrapolation to humans of the findings in two separate, controlled animal studies. This position is compatible with that of NIOSH concerning the prior demonstration of carcinogenicity in at least two animal studies.

A major question of occupational carcinogenesis relates to the extrapolation of results of animal experimentation to humans. The basis of numerous objections to the proposals is that, even assuming the validity of animal experiments, such do not furnish sufficient evidence that the substances involved are carcinogenic to humans. Extrapolation of results

obtained by animal experimentation is alleged to be vitiated by several considerations: (a) That certain cancers are specific only to some species; (b) that the conditions of animal experiments are out of proportion to, and not consistent with, conditions prevailing in industrial exposure; and (c) that no cancers have yet been detected in humans exposed to the substances. For those substances whose metabolism is understood, and is similar in both animals and man, the fact that they induce cancers in animals warrants the expectation that they will induce cancers in men. This applies to the substances which cause urinary bladder cancers in animals acting, not directly, but indirectly through the mediation of metabolites formed both in experimental animals and in exposed workers. This is also true of those substances which apparently require no metabolic alteration but attack a particular biologic system (e.g., respiratory tract, alimentary canal) which is similar in both animals and humans.

The objections raise the much broader issue of human exposure to a chemical which is only known to have caused cancers in experimental animals.

It is important to note that some opponents of the regulation of such chemicals do not advocate treating them as if they were harmless with respect to carcinogenic potential. Several employers, for instance insist that such substances must be treated with "care" or "respect," while also insisting that they call for significantly less protection than those substances known to be human carcinogens.

We think it improper to afford less protection to workers when exposed to substances found to be carcinogenic only in experimental animals. Once the carcinogenicity of a substance has been demonstrated in animal experiments, the practical regulatory alternatives are to consider them either non-carcinogenic or

carcinogenic to humans, until evidence to the contrary is produced. The first alternative would logically require, not relaxed controls on exposure, but exclusion from regulation. The other alternative logically leads to the treatment of a substance as if it was known to be carcinogenic in man.

We agree with the Director of NIOSH, and the report to the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens to the Surgeon General, U.S. Public Health Service, April 22, 1970, that the second alternative is the responsible and correct one. This decision accords with the work practices of some who object to the proposed regulation. For example, although the Pharmaceutical Manufacturers Association argues for the exclusion of research laboratories from the standard, it states as its ground the fact that employees in Pharmaceutical research are taught to work with all chemicals under the assumption that they are dangerous, unless it is specifically known that they are not.

(3) *The petition, zero tolerance, and permit system.* The petition of Oil, Chemical and Atomic Workers Union (OCAW) and Health Research Group (HRG) for an emergency temporary standard on ten substances proceeds on the assumption that any exposure to any amount of a carcinogenic substance must be prevented. Accordingly, it proposes a standard of zero tolerance permitting no exposure whatsoever. This objective would be accomplished by means of a permit system and frequent monitoring and reporting.

We agree with the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens that a safe level of human exposure to any of the 14 carcinogens cannot be established by application of present knowledge. But we are not prepared to

draw from this state of knowledge the conclusion that such levels do not exist. First, it is the professional opinion of many knowledgeable people that as yet undetermined safe levels of exposure possibly do exist. Also, a conclusion that safe levels do not exist seems questionable in view of other studies, some in the area of carcinogenicity which demonstrated that below a certain amount of a single or cumulative dosage, no detectable harm is caused, or if harm is caused, the extent of such harm will be of no practicable importance because the latency period prior to manifestation of harmful effects will be of greater duration than the normal lifespan of man. Secondly, no possible exposure to the carcinogens under any circumstances could only be guaranteed by a total ban on the manufacture, use (even for cancer research), and transportation of the substances. As long as the substances are used, exposure to some amounts may occur because of breakdown of equipment or human error. Accordingly, the intent of the standards is to reduce exposure of workers to any of the listed substances to the maximum extent practicable consistent with continued use.

Numerous objections have challenged the authority for, and the administrative feasibility of, the permit system proposed on July 16, 1973 (38 FR 18902). It is argued, for instance, that the Act requires the promulgation of general standards, in accordance with the procedures prescribed in section 6 of the Act, while the proposed permits would be tailored to particular users, and would be issued by a different procedure.

Another objection argues that a permit system, to be effective, would require authority to stop an operation involving a carcinogen by administrative action, in contravention of the statutory scheme which con-

templates judicial determinations resulting in the cessation of an operation.

With regard to feasibility, it is pointed out that a multitude of permits would be required, and that, therefore, the implementation of a permit system would require substantial resources and several years.

It has been made clear that there are numerous uses and processes involving carcinogens. It appears, for instance, that there are 800 to 1800 users of 4,4′-methylene bis(2-chloroaniline) alone. The investigations and evaluations of thousands of work situations involving a carcinogen, and the completion of the procedures, possibly including hearings, for the granting of the permits, would require many years and the diversion of substantial resources, even if available, from other serious occupational safety and health problems.

After considering the administrative and legal aspects of a permit system, as against those of general standards enforced by the use of the current enforcement tools of the Act, the decision has been made not to adopt a permit system.

The requirement in the adopted standards for employers to report the uses of carcinogens and the nature of operations involved, together with incidents of releases of carcinogens, will permit significant administrative surveillance.

(4) *Mixtures.* The proposal for this rulemaking proceeding, like the Emergency Temporary Standard, excludes from the scope of the standard mixtures containing less than specified percentages of the 14 listed substances. The specific figure as a cutoff point derives from the regulations of the Commonwealth of Pennsylvania and England, which also regulate exposure to carcinogens, and apparently have faced

the same administrative difficulties confronting OSHA. It is recognized that some of the carcinogens may be used in minute amounts with other substances, or may appear as unintended, undesired byproducts or contaminants of processes. Some of the substances are used in minute amounts in cancer research laboratories, and for medical purposes. The College of American Pathologists, for instance, points out that for years pathology laboratories and physicians have used benzidine and/or benzidine dihydrochloride for diagnostic purposes. The American Home Products Corporation calls attention to the use of beta-Propiolactone for the sterilization of vaccines and tissue grafts. Koppers, Inc., requests an exemption in some form for materials, such as coal tar and coal tar products, that contain trace amounts of some carcinogens as by-products or contamination of processes essential to our industrial society. It states that the application of the proposed standard to crude mixtures, such as coal tar and coal tar products, without any exemption, would have the effect of closing down large segments of industry, such as steelmaking, wood preserving, roofing, aluminum reduction, and possibly even power plants.

The adopted standards retain the proposed exclusion of solid or liquid mixtures containing less than 1 percent, by weight or volume, of eight of the carcinogens. Solid or liquid mixtures containing 4-Aminodiphenyl, Benzidine (and its salts), 4-Nitrobiphenyl, beta-Naphthylamine, bis-Chloromethyl ether and Methyl chloromethyl ether are excluded only if they contain less than 0.1 percent of those substances. Finally, an exclusion is provided in the destructive distillation of carbonaceous materials, for alpha-Naphthylamine and beta-Naphthylamine, which may occur in such processes.

The overall purpose of all the exclusions is to avoid substantial obstruction, if not stoppage, of the use of

many processes and products which are considered useful in industy and even in cancer research, and about which the record contains very little information. We do not know how many such products and processes there are, nor the availability of substitutes for all of the carcinogens involved, nor the effect of the other components of a mixture on the carcinogenic potentiality of the small amounts of the carcinogen involved. The exclusionary percentage for mixtures containing 4-Aminodiphenyl, Benzidine, 4-Nitrobiphenyl, beta-Naphthylamine, bis-Chloromethyl ether and Methyl chloromethyl ether has been lowered from 1 percent to 0.1 percent because these substances are known to be potent human carcinogens.

The exclusion for the destructive distillation of carbonaceous materials is for the purpose of avoiding the extreme consequences to the segments of the industry using vigorous thermal processes at a time when a separate standard-setting proceeding on coke oven emissions will afford the opportunity for a more in-depth consideration of this whole area (see 38 FR 26207). The exclusion of the mixtures rests, not on a finding that the mixtures are non-carcinogenic, but rather on a decision not to regulate them at this time, on the basis of the record of this proceeding.

(5) *Number of Standards Needed.* Another objection to the proposals is that the standard "lumps together" many different substances with different chemicals and physical properties, different physical states, different biological properties and different uses. There is merit in this objection. Accordingly, 14 standards are adopted, one for each substance listed in the proposal of July 16, 1973.

These standards recognize and provide for different uses and operations involving the regulated carcinogens. Ethyleneimine and beta-Propiolactone are

immediately corrosive, and provisions are made in the standards for these materials for deluge showers and eye wash fountains, located near places where exposures might be expected. Principally volatile materials will not be present long enough for routine washing or showering to have effect as a protective measure. Thus, a requirement to wash on each exit, and shower at the end of the day, would not offer any significant protection to employees working in areas where the volatile materials, Methyl chloromethyl ether, bis-Chloromethyl ether, Ethyleneimine and beta-Propiolactone, are present in a closed system or closed system transfer operation. Trace amounts that might be adsorbed onto exposed skin vaporize long before the employee would routinely wash or shower. Wash requirements are retained for these materials in isolated system operations because the closed confinement of glovebox gloves would inhibit vaporization if a leak should occur.

Special provisions are made for premix operations involving 4,4 Methylene-bis (2-chloroaniline) and liquid prepolymer. These premix solutions, frozen or otherwise, are packaged in such a manner and used only after the 4,4'-Methylene-bis(2-chloroaniline) and the prepolymer have started to react. No dust hazard exists and a vapor hazard is unlikely. For this reason, the standard requires only protective clothing such as smocks, coveralls, or long-sleeved shirts and pants, and gloves. This, we believe, will afford adequate protection for these workers.

On the other hand, some of the differences pointed out do not require different treatment. There are basically two strategies of control, regardless of the physical state of a carcinogen. One is to isolate the carcinogen and the other is to isolate the areas of possible exposure. In cases of isolated systems, the

physical state of the carcinogen may be disregarded for practical purposes. When a system is isolated and fully closed so that the substances cannot escape into the work environment, it does not matter if the substance in it is a solid, liquid, or gas. An isolated system achieved by engineering controls is the preferred approach and the basic approach adopted in the standards. That is, the preferred method of control is engineering control, such as by closed systems, mechanical seals, remote controls, and local exhaust ventilation. This approach most effectively isolates employees from potential contamination.

This is the reason for the ban on open vessel operations. Because of consideration of feasibility, special provisions are made for laboratory hoods and transfer point operations, and additional work practice requirements are made applicable to them.

When protection is afforded by means of personal protective equipment, it is thought best to require body coverage, regardless of the physical state of the substance and its path of travel into the body. The reason for such personal protection is that even if a substance is considered to do harm only when ingested or inhaled, it is prudent to provide protective garments to be discarded after use, so that a worker may not accidentally inhale or ingest contaminants adhering to his clothing or body. This precaution is reasonable, especially since the standards do not require full impervious air-supplied suits. OSHA agrees with the many comments that a full impervious air-supplied suit is cumbersome, while impervious garments with air-supplied hoods are adequate and more comfortable to the workers when used in accordance with the work practice provisions of these standards.

(6) *Research laboratories.* Numerous objections have been made to the proposal for identical treatment of

industrial use and laboratory use of the carcinogens. There are essentially three objections: (a) That laboratories use very small amounts of the substances; (b) that work is done by, or under the direction of, highly trained personnel; and (c) that, in the absence of an exemption or other special consideration, the standard as proposed would obstruct, and possibly even prevent much research including cancer research.

These objections are well-taken and special provisions are made applicable to laboratory activities. The *provisions are derived from* the Minimum Safety Guidelines for Research in Cancer (Part 1, For Research Involving Chemical Carcinogens), prepared in draft form by the Cancer Research Safety Committee of the National Cancer Institute. In addition, it is to be noted that the exclusion provisions for certain mixtures may, by themselves, make a whole standard inapplicable.

Personnel engaged in animal support activities must necessarily handle animals exposed in connection with experiments involving one or more of the carcinogens. Such support activities include the feeding of animals, cleaning of cages and the animal room, and caring for the animals, including weighing operations. Such close animal contact involves potential exposure both to a carcinogen and to metabolites of the carcinogen and therefore requires the more stringent controls for such personnel provided in the standards.

(7) *Signs and labels.* The controversy with regard to signs and labels centers on whether the word "cancer" should be used. We believe that a diluted form of warning will not suffice. We appreciate the concern of employers with the reactions of their employees and the users of their products. But we consider of paramount importance that a worker should be fully apprised and realize the possible risks in-

volved in his occupation. The use of the word "suspect" in the phrase "Cancer-Suspect" follows the revised Emergency Temporary Standard issued July 27, 1973. Coupled with the information and training requirement in the standard, it appears to provide the necessary warning to employees.

(8) *Information and training.* Employers are responsible for providing indoctrination and training to their employees on the nature of the carcinogenic hazards in the establishment, and the precautions to be used when working with or in the presence of the carcinogens. Information on the training and education to be provided to employees is specified in each of the standards for a carcinogenic agent.

(9) *Monitoring.* No provisions for specific techniques or instruments for environmental monitoring are contained in the standards adopted. OSHA has requested NIOSH to develop, on a priority basis, methods for determining qualitative and quantitative amounts of the carcinogens in the workplace.

(10) *Medical surveillance.* Medical surveillance by a physician is required in the standards prior to assignment, at yearly intervals thereafter and whenever known or possible exposure to a carcinogen has occurred. Medical surveillance is considered necessary because of the long latency period inherent in occupational carcinogenesis, since initiation of exposure and induction of cancer are not synchronous events.

(11) *Reports and records.* The standards require reports concerning the use of carcinogens, the number of employees in regulated areas, and incidents resulting in the release of a carcinogen in an area where employees may be potentially exposed. The standards also require records of medical examinations of employees. The reports and records are considered

necessary in order to monitor the effectiveness of the standards in protecting employees against occupational cancer and in order to obtain information, on a continuing basis, concerning the hazards found in the use of the carcinogens.

Accordingly, upon consideration of the whole record of this proceeding, 29 CFR Part 1910 is amended by revising § 1910.93c and by adding new §§ 1910.93d through 1910.93p, reading as follows:

§ 1910.93*l* *Ethyleneimine.*

(a) *Scope and application.* (1) This section applies to any area in which Ethyleneimine, Chemical Abstracts Service Registry Number 151564 is manufactured, processed, repackaged, released, handled, or stored, but shall not apply to transshipment in sealed containers, except for the labeling requirements under paragraphs (e)(2), (3), and (4) of this section.

(2) This section shall not apply to solid or liquid mixtures containing less than 1.0 percent by weight or volume of Ethyleneimine.

(b) *Definitions.* For the purposes of this section: (1) "Absolute filter" is one capable of retaining 99.97 percent of a mono disperse aerosol of 0.3 μm particles.

(2) "Authorized employee" means an employee whose duties require him to be in the regulated area and who has been specifically assigned by the employer.

(3) "Clean change room" means a room where employees put on clean clothing and/or protective equipment in an environment free of Ethyleneimine. The clean change room shall be contiguous to and have an entry from a shower room, where the shower room facilities are otherwise required in this section.

(4) "Closed system" means an operation involving Ethyleneimine where containment prevents the release

of Ethyleneimine into regulated areas, non-regulated areas, or the external environment.

(5) "Decontamination" means the inactivation of Ethyleneimine or its safe disposal.

(6) "Director" means the Director, National Institute for Occupational Safety and Health, or any person directed by him or the Secretary of Health, Education, and Welfare to act for the Director.

(7) "Disposal" means the safe removal of Ethyleneimine from the work environment.

(8) "Emergency" means an unforeseen circumstance or set of circumstances resulting in the release of Ethyleneimine which may result in exposure to or contact with Ethyleneimine.

(9) "External environment" means any environment external to regulated and nonregulated areas.

(10) "Isolated system" means a fully enclosed structure other than the vessel of containment of Ethyleneimine, which is impervious to the passage of Ethyleneimine, and which would prevent the entry of Ethyleneimine into regulated areas, nonregulated areas, or the external environment, should leakage or spillage from the vessel of containment occur.

(11) "Laboratory type hood" is a device enclosed on three sides and the top and bottom, designed and maintained so as to draw air inward at an average linear face velocity of 150 feet per minute with a minimum of 125 feet per minute; designed, constructed, and maintained in such a way that an operation involving Ethyleneimine within the hood does not require the insertion of any portion of any employees' body other than his hands and arms.

(12) "Nonregulated area" means any area under the control of the employer where entry and exit is neither restricted nor controlled.

(13) "Open-vessel system" means an operation involving Ethyleneimine in an open vessel, which is not in an isolated system, a laboratory type hood, nor in any other system affording equivalent protection against the entry of Ethyleneimine into regulated areas, nonregulated areas, or the external environment.

(14) "Protective clothing" means clothing designed to protect an employee against contact with or exposure to Ethyleneimine.

(15) "Regulated area" means an area where entry and exit is restricted and controlled.

(c) *Requirements for areas containing Ethyleneimine.* A regulated area shall be established by an employer where Ethyleneimine is manufactured, processed, used, repackaged, released, handled or stored. All such areas shall be controlled in accordance with the requirements for the following category or categories describing the operation involved: (1) *Isolated systems.* Employees working with Ethyleneimine within an isolated system, such as a "glove box" shall wash their hands and arms upon completion of the assigned task and before engaging in other activities not associated with the isolated system.

(2) *Closed system operation.* Within regulated areas where Ethyleneimine is stored in sealed containers or contained in a closed system, including piping systems, with any sample ports or openings closed while Ethyleneimine is contained within: Access shall be retricted to authorized employees only.

(3) *Open vessel system operations.* Open vessel system operations as defined in paragraph (b) (13) of this section are prohibited.

(4) *Transfer from a closed system, charging or discharging point operations, or otherwise opening a*

closed system. In operations involving "laboratory type hoods," or in locations where Ethyleneimine is contained in an otherwise "closed system," but is transferred, charged, or discharged into other normally closed containers, the provisions of this subparagraph shall apply. (i) Access shall be restricted to authorized employees only;

(ii) Each operation shall be provided with continuous local exhaust ventilation so that air movement is always from ordinary work areas to the operation. Exhaust air shall not be discharged to regulated areas, nonregulated areas or the external environment unless decontaminated. Clean makeup air shall be introduced in sufficient volume to maintain the correct operation of the local exhaust system.

(iii) Employees shall be provided with, and required to wear, clean, full body protective clothing (smocks, coveralls, or long-sleeved shirt and pants), and gloves prior to entering the regulated area.

(iv) Employees engaged in Ethyleneimine handling operations shall be provided with and required to wear and use a fullface, supplied air respirator, of the continuous flow or pressure-demand type, in accordance with § 1910.134.

(v) Prior to each exit from a regulated area, employees shall be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers shall be identified, as required under paragraphs (e)(2), (3), and (4) of this section.

(vi) Drinking fountains are prohibited in the regulated area.

(5) *Maintenance and decontamination activities.* In cleanup of leaks or spills, maintenance or repair operations on contaminated systems or equipment, where direct contact with Ethyleneimine could result, each authorized employee entering that area shall: (i) Be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood in accordance with § 1910.134.

(ii) Be decontaminated before removing the protective garments and hood;

(iii) Be required to shower upon removing the protective garments and hood.

(6) *Laboratory activities.* The requirements of this subparagraph shall apply to research and quality control activities involving the use of Ethyleneimine. (i) Mechanical pipetting aids shall be used for all pipetting procedures.

(ii) Experiments, procedures and equipment which could produce aerosols shall be confined to laboratory-type hoods or glove boxes.

(iii) Surfaces on which Ethyleneimine is handled shall be protected from contamination.

(iv) Contaminated wastes and animal carcasses shall be collected in impervious containers which are closed and decontaminated prior to removal from the work area. Such wastes and carcasses shall be incinerated in such a manner that no carcinogenic products are released.

(v) All other forms of Ethyleneimine shall be inactivated prior to disposal.

(vi) Laboratory vacuum systems shall be protected with high-efficiency scrubbers.

(vii) Employees engaged in animal support activities shall be *(a)* provided with, and required to wear, a complete protective clothing change, clean each day, including coveralls or pants and shirt, foot covers, head covers, gloves, and appropriate respiratory protective equipment or devices; and

(b) Prior to each exit from a regulated area, employees shall be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers shall be identified as required under paragraphs (e)(2), (3), and (4) of this section.

(c) Required to shower after the last exit of the day.

(viii) Employees, other than those engaged only in animal support activities, each day shall be *(a)* provided with and required to wear a clean change of appropriate laboratory clothing, such as a solid front gown, surgical scrub suit, or fully buttoned laboratory coat.

(b) Prior to each exit from a regulated area, employees shall be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The containers shall be identified as required under paragraphs (e)(2), (3), and (4) of this section.

(c) Required to wash hands, forearms, face and neck upon each exit from the regulated area close to the point of exit, and before engaging in other activities.

(ix) Air pressure in laboratory areas and animal rooms where Ethyleneimine is handled and bioassay

studies are performed shall be negative in relation to the pressure in surrounding areas. Exhaust air shall not be discharged to regulated areas, nonregulated areas or the external environment unless decontaminated.

(x) There shall be no connection between regulated areas and any other areas through the ventilation system.

(xi) A current inventory of Ethylenemine shall be maintained.

(xii) Ventilated apparatus, such as laboratory type hoods, shall be tested at least semi-annually or immediately after ventilation modification or maintenance operations, by personnel fully qualified to certify correct containment and operation.

(d) *General regulated area requirements*—(1) *Employee identification.* A daily roster of employees entering regulated areas shall be established and maintained. The rosters or a summary of the rosters, shall be retained for a period of 20 years. The rosters and/or summaries shall be provided upon request to authorized representatives of the Assistant Secretary and the Director. In the event that the employer ceases business without a successor, rosters shall be forwarded by registered mail to the Director.

(2) *Emergencies.* In an emergency, immediate measures including, but not limited to, the requirements of subdivisions (i), (ii), (iii), (iv), and (v) of this subparagraph shall be implemented. (i) The potentially affected area shall be evacuated as soon as the emergency has been determined.

(ii) Hazardous conditions created by the emergency shall be eliminated and the potentially affected area shall be decontaminated prior to the resumption of normal operations.

(iii) Special medical surveillance by a physician shall be instituted within 24 hours for employees present in the potentially affected area at the time of the emergency. A report of the medical surveillance and any treatment shall be included in the incident report, in accordance with paragraph (f)(2) of this section.

(iv) Where an employee has a known contact with Ethyleneimine, such employee shall be required to shower as soon as possible, unless contraindicated by physical injuries.

(v) An incident report on the emergency shall be reported as provided in paragraph (f)(2) of this section.

(vi) Emergency deluge showers and eyewash fountains supplied with running potable water shall be located near, within sight of, and on the same level with locations where a direct exposure of Ethyleneimine would be most likely as a result of equipment failure, or improper work practice.

(3) *Hygiene facilities and practices.* (i) Storage or consumption of food, storage or use of containers of beverages, storage or application of cosmetics, smoking, storage of smoking materials, tobacco products or other products for chewing, or the chewing of such products, are prohibited in regulated areas.

(ii) Where employees wear protective clothing and equipment clean change rooms shall be provided, in accordance with § 1910.141(e), for the number of such employees required to change clothes.

(iii) Where toilets are in regulated areas, such toilets shall be in a separate room.

(iv) Where employees are required by this section to wash, washing facilities shall be provided in accordance with § 1910.141(d)(1) and (2)(ii) through (vii).

(v) Where employees are required by this section to shower, shower facilities shall be provided in accordance with § 1910.141(d)(3).

(4) *Contamination control.* (i) Regulated areas, except for outdoor systems, shall be maintained under pressure negative with respect to nonregulated areas. Local exhaust ventilation may be used to satisfy this requirement. Clean makeup air in equal volume shall replace air removed.

(ii) Any equipment, material, or other item taken into or removed from a regulated area shall be done so in a manner that does not cause contamination in nonregulated areas or the external environment.

(iii) Decontamination procedures shall be established and implemented to remove Ethyleneimine from the surfaces of materials, equipment and the decontamination facility.

(e) *Signs, information and training*—(1) *Signs.* (i) Entrances to regulated areas shall be posted with signs bearing the legend:

CANCER-SUSPECT AGENT
AUTHORIZED PERSONNEL ONLY

(ii) Entrances to regulated areas containing operations covered in paragraph (e)(5) of this section shall be posted with signs bearing the legend:

CANCER-SUSPECT AGENT EXPOSED IN THIS AREA IMPERVIOUS SUIT INCLUDING GLOVES, BOOTS, AND AIR-SUPPLIED HOOD REQUIRED AT ALL TIMES, AUTHORIZED PERSONNEL ONLY

(iii) Appropriate signs and instructions shall be posted at the entrance to, and exit from, regulated areas, informing employees of the procedures that must be followed in entering and leaving a regulated area.

(2) *Container contents identification.* (1) Containers of Ethyleneimine and containers required under

paragraphs (e)(4)(v) and (e)(6)(vii) (*b*), and (e) (6) (viii)(*b*) of this section which are accessible only to, and handled only by, authorized employees, or by other employees trained in accordance with subparagraph (5) of this paragraph, may have contents identification limited to a generic or proprietary name, or other proprietary identification, of the carcinogen and percent.

(ii) Containers of Ethyleneimine and containers required under paragraphs (e)(4)(v), (e)(6)(vii)(*b*), and (e)(6)(viii)(*b*) of this section which are accessible to, or handled by employees other than authorized employees or employees trained in accordance with subparagraph 5 of this paragraph shall have contents identification which includes the full chemical name and Chemical Abstracts Service Registry number as listed in paragraph (a)(1) of this section.

(iii) Containers shall have the warning words "CANCER-SUSPECT AGENT" displayed immediately under or adjacent to the contents identification.

(iv) Containers which have Ethyleneimine contents with corrosive or irritating properties shall have label statements warning of such hazards, noting, if appropriate, particularly sensitive or affected portions of the body.

(3) *Lettering.* Lettering on signs and instructions required by subparagraph (1) of this paragraph shall be a minimum letter height of 2 inches. Labels on containers required under this section shall not be less than ½ the size of the largest lettering on the package, and not less than 8 point type in any instance: *Provided*, That no such required lettering need be more than 1 inch in height.

(4) *Prohibited statements.* No statement shall appear on or near any required sign, label, or instruction which contradicts or detracts from the effect of any required warning, information or instruction.

(5) *Training and indoctrination.* (i) Each employee prior to being authorized to enter a regulated area, shall receive a training and indoctrination program including, but not necessarily limited to: *(a)* The nature of the carcinogenic hazards of Ethyleneimine, including local and systemic toxicity;

(b) The specific nature of the operation involving Ethyleneimine which could result in exposure;

(c) The purpose for and application of the medical surveillance program, including as appropriate, methods of self-examination;

(d) The purpose for and application of decontamination practices and purposes;

(e) The purpose for and significance of emergency practices and procedures;

(f) The employee's specific role in emergency procedures;

(g) Specific information to aid the employee in recognition and evaluation of conditions and situations which may result in the release of Ethyleneimine;

(h) The purpose for and application of specific first aid procedures and practices;

(i) A review of this section at the employee's first training and indoctrination program and annually thereafter.

(ii) Specific emergency procedures shall be prescribed, and posted, and employees shall be familiarized with their terms, and rehearsed in their application.

(iii) All materials relating to the program shall be provided upon request to authorized representatives of the Assistant Secretary and the Director.

(f) *Reports*—(1) *Operations.* Not later than March 1, 1974, the information required in subdivisions (i), (ii), (iii), and (iv) of this subparagraph shall be reported in writing to the nearest OSHA Area Director. Any changes in such information shall be similarly reported in writing within 15 calendar days of such change. (i) A brief description and in-plant location of the area(s) regulated and the address of each regulated area;

(ii) The name(s) and other identifying information as to the presence of Ethyleneimine in each regulated area;

(iii) The number of employees in each regulated area, during normal operations including maintenance activities and

(iv) The manner in which Ethyleneimine is present in each regulated area; e.g. whether it is manufactured, processed, used, repackaged, released, stored, or otherwise handled.

(2) *Incidents.* Incidents which result in the release of Ethyleneimine into any area where employees may be potentially exposed shall be reported in accordance with this subparagraph. (i) A report of the occurrence of the incident and the facts obtainable at that time including a report on any medical treatment of affected employees shall be made within 24 hours to the nearest OSHA Area Director.

(ii) A written report shall be filed with the nearest OSHA Area Director within 15 calendar days therafter and shall include: *(a)* A specification of the amount of material released, the amount of time involved, and an explanation of the procedure used in determining this figure;

(b) A description of the area involved, and the extent of known and possible employee exposure and area contamination, and

(c) A report of any medical treatment of affected employees, and any medical surveillance program implemented; and

(d) An analysis of the circumstances of the incident, and measures taken or to be taken, with specific completion dates, to avoid further similar releases.

(g) *Medical surveillance.* At no cost to the employee, a program of medical surveillance shall be established and implemented for employees considered for assignment to enter regulated areas, and for authorized employees. (1) *Examination.* (i) Before an employee is assigned to enter a regulated area, a preassignment physical examination by a physician shall be provided. The examination shall include the personal history of the employee, family and occupational background, including genetic and environmental factors.

(ii) Authorized employees shall be provided periodic physical examinations, not less often than annually, following the preassignment examination.

(iii) In all physical examinations, the examining physician shall consider whether there exist conditions of increased risk, including reduced immunological competence, those undergoing treatment with steroids or cytotoxic agents, pregnancy and cigarette smoking.

(2) *Records.* (1) Employers of employees examined pursuant to this paragraph shall cause to be maintained complete and accurate records of all such medical examinations. Records shall be maintained for the duration of the employee's employment. Upon termination of the employee's employment, including retirement or death, or in the event that the employer ceases business without a successor, records, or notarized true copies thereof, shall be forwarded by registered mail to the Director.

(ii) Records required by this paragraph shall be provided upon request to authorized representatives of the Assistant Secretary or the Director; and upon request of an employee or former employee, to a physician designated by the employee or to a new employer.

(iii) Any physician who conducts a medical examination required by this paragraph shall furnish to the employer a statement of the employee's suitability for employment in the specific exposure.

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